Clinical Data

1075 W. Lambert Road Suite D
Brea, CA 92821
T (714) 672-3553 F (714) 672-3554

MAY 21 2004

K033983

Summary of 510(k) Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Vitalab Iron Reagent Kit and the Vitalab Selectra Analyzer are used as a system for the quantitative analysis of total iron in serum and plasma. Iron results may be used for the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. The Vitalab Iron Reagent measures iron photometrically. Iron in the specimen is released from the transferrin using acetic acid. This iron is reduced to the ferrous cation and is bound by ferene, which is a sensitive iron indicator. The increase in absorbance at 578 nm is proportional to the iron concentration of the sample.

Vitalab Iron Reagent Kit, which contains an iron calibrator, is equivalent to the Beckman Iron Reagent Kit, calibrated with the Synchron Multi-Calibrator, which are marketed by Beckman Coulter, Inc. of Brea, CA.

The effectiveness of Vitalab Iron Reagent Kit and the Vitalab Selectra is shown in the following studies.

The recovery of iron using the Vitalab Iron Reagent is linear from 10 to at least 1000 µg/dL, as shown by the recovery of linearity standards that span the linear range. Least squares regression statistics compare recoveries to standard concentrations. These statistics are shown below.

(Vitalab Recoveries) = 0 µg/dL + 1.017 x (Concentration), r = 1.0000, sy.x = 2.3 mg/dL, n = 44

Precision is demonstrated by the replicate assay of commercially available control serum. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of Iron Recoveries in µg/dL

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	66	57	0.9	1.6%	1.5	2.7%
Serum 2	66	158	0.9	0.6%	3.0	1.9%
Serum 3	66	260	1.0	0.4%	5.2	2.0%

Mixed serum and plasma specimens collected from adult patients were assayed for iron using the Vitalab Selectra and another commercially available method. Results were compared by Deming regression and the following statistics were obtained.

Selectra = 1.1 µg/dL + 0.988 x Competitive Reagent
$s_{(y.x)}$ = 2.3 µg/dL n = 118 range = 9 - 287 µg/dL

The claimed detection limit is documented through the repetitive assay of a diluted serum pool. The observed standard deviation of a 30 replicate within run precision study is 2.8 µg/dL, which supports a detection limit claim of 8.2 µg/dL iron.

The 14 day onboard reagent stability and 7 day calibration stability claims are documented through the assay of serum controls over the claimed periods. In all cases, statistical estimates of coefficient of variation are less than 2%.

Wynn Stocking
Manager of Regulatory Affairs
Clinical Data, Brea CA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 21 2004

Clinical Data, Inc.
c/o Mr. Ned Devine
Responsible Official
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, MI 49548

Re: k033983
Trade/Device Name: Vitalab Iron Reagent and Calibrator
Regulation Number: 21 CFR 862.1410
Regulation Name: Iron (non-heme) test system
Regulatory Class: Class I
Product Code: JIY
Dated: May 10, 2004
Received: May 13, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

K033983

Indications for Use

510(k) Number (if known): K033983

Device Name: Vitalab Iron Reagent and Calibrator

Indications For Use:

The Vitalab Iron Reagent Kit, which contains both reagent and calibrator, is intended for use with the Vitalab Selectra E Analyzer as a system for the quantitative determination of total iron in serum and plasma. Iron results may be used for the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K033983